# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Daniel R. PAVLIK et al. Examiner: Heller, Tammie K.

Serial No.: 10/717,721 Group Art: 3766

Filing Date: November 20, 2003 Docket No.: P0020005.00

Conf. No. 8711

Title: NOVEL WELDED JUNCTION FOR MEDICAL ELECTRICAL LEADS

# Appeal Brief

Mail Stop Appeal Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

The following is submitted in response to the Panel Decision mailed July 6, 2010.

Any required fee will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.16, 1.17, 1.136(a), or any additional fees to Deposit Account 13-2546.

# Real party in interest

The real party in interest in this application is Medtronic, Inc, assignee of the application.

# Related appeals and interferences

None

## III. Status of the claims

Claims 1-5, 7-13, 25 and 29 are pending in the present application. Claims 8, 14-24 and 26-28 are cancelled. No claims are amended or added. Claims 1-5, 7-13, 25 and 29 stand rejected over Westlund. Claims 1-5, 7-13 and 25 stand rejected over Ley and Bush. Claim 29 is indicated to be allowable over Ley and Bush.

## IV. Status of amendments

The Amendment After Final filed 5 April, 2010 has been entered in conjunction with the Notice of Appeal. The Claims Appendix reflects the claims as amended.

# V. Summary of claimed subject matter

Claims 1-5, 7-13, 25 and 29 stand rejected. The subject matter of these claims is summarized below, by means of a discussion of the independent claims 1 and 29. Patentability of the dependent claims is not separately argued.

# Claim 1

Claim 1 sets forth a medical electrical lead. The lead is generally illustrated in Figure 1 and is generally described in paragraphs [0014 and 15].

The lead comprises a component including a surface and a groove formed in the surface. The component is illustrated at 600A in Figure 6A. The groove is illustrated at 620A in figure 6. The component and groove are described in paragraph [0019].

The lead further includes a conductor, the conductor extending within the lead and including a plurality of wire strands cabled together positioned within the groove of the component. The conductor is illustrated at 650 in Figure 6A and in more detail at 500 in Figure 5. The conductor is described in paragraphs [0018 – 19]. The relationship between the conductor and the groove is illustrated in Figure 6A and discussed in paragraph [0019].

The lead further comprises a resistance weld formed between the conductor and the component. Figure 6A illustrates the conductor and the component as located in a resistance welder. The weld itself is illustrated in Figure 6C and described in Paragraph [0019].

The groove includes a depth and the conductor positioned within the groove includes a pre-weld diameter, the pre-weld diameter being greater than the depth of the groove. This relationship is illustrated in Figure 6A and discussed in paragraph [0019].

### Claim 29

Claim 29 sets forth a medical electrical lead. The lead is generally illustrated in Figure 1 and is generally described in paragraphs [0014 and 15].

The lead comprises a component comprising a substantially tubular body having an inner surface and a groove formed in the inner surface. This version of the component is illustrated at 600B in Figure 6B. The groove is illustrated at 620B in figure 6B. The component and groove are described in paragraph [0019].

The lead further comprises a conductor comprising a plurality of wire strands cabled together, the conductor extending within the lead and positioned within the groove of the component. The conductor is illustrated at 650 in Figure 6B and in more detail at 500 in Figure 5. The conductor is described in paragraphs [0018 – 19]. The

relationship between the conductor and the groove is illustrated in Figure 6Band discussed in paragraph [0019].

The lead further comprises a resistance weld formed between the conductor and the component. Figure 6B illustrates the conductor and the component as located in a resistance welder. The weld itself is illustrated in Figure 6C and described in Paragraph 100191.

The groove includes a depth and the conductor positioned within the groove includes a pre-weld diameter, the pre-weld diameter being greater than the depth of the groove. This relationship is illustrated in Figure 6A and discussed in paragraph [0019].

# VI. Grounds of rejection to be reviewed on appeal

# A. Rejection Under 35 U.S.C. § 103 - Westlund (U.S. 6,643,550).

Claims 1-5, 8-13, 25 and 29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Westlund (U.S. 6,643,550). This rejection is respectfully traversed.

# B. Rejection Under 35 U.S.C. § 103 - Rejection over Ley (U.S. 6, 912,423) in view of Bush (U.S. 5,385,578)

Claims 1-6, 8 - 13, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ley (U.S. 6, 912,423) in view of Bush (U.S. 5,385,578). This rejection is also respectfully traversed.

# VII. Argument

# A. Rejection Under 35 U.S.C. § 103 - Westlund (U.S. 6,643,550).

Claims 1-5, 8-13, 25 and 29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Westlund (U.S. 6,643,550). This rejection is respectfully traversed.

The rejected claims require a component including a surface and a groove formed in the surface; a conductor comprising a plurality of wire strands cabled together, the conductor extending within the lead and positioned within the groove of the component; and a resistance weld formed between the conductor and the component; wherein the groove includes a depth and the conductor positioned within the groove includes a pre-weld diameter, the pre-weld diameter (of the multi-strand conductor) being greater than the depth of the groove. The rules of claim interpretation and common English usage thus require that the strands (plural) of the cable are welded in the previously designated groove (singular). This is clearly not shown in Westlund. Because the rejection depends upon the erroneous assertion that Westlund does show this feature, the rejection is correspondingly improper. Withdrawal of the rejection is thus respectfully requested.

The Examiner argues that Westlund teaches such a cabled, multi-strand conductor (or a plurality of wire strands cabled together, as the Examiner would have it), in the form of the conductors 195, shown in cut-away view in Figures 10 C and 10D. This observation is respectfully asserted to be clearly factually incorrect. These figures illustrate a multi-filar coil comprising individual single strand solid conductors 195. Theses conductors/strands are not cabled together as required by the claims. As used in the specification of the application and as understood in the relevant art of implantable leads, the structure of a cabled conductor is clearly distinct from multi-filar solid strand conductor coil of the type disclosed in Westlund.

A conductor formed of cabled strands is what the claim requires and Westlund doesn't show such a conductor. The terms: cable, cable conductor and cabled conductor are all well understood by those of skill in the art to be distinct from coiled conductors or conductor coils of the types shown in Westlund. Examples of the usage

of the term "cable" or "cabled" to describe a conductor within the relevant art are included in the Appendix below. Because they are issued US patents, they are self authenticating and require no accompanying Affidavits. They are cited only to show common usage. An interpretation of a claim limitation that is contrary to both its usage in the patent specification and its usage in the relevant art is respectfully asserted to be per-se unreasonable. Because the rejection depends upon this unreasonable interpretation, it is respectfully asserted to be clearly improper.

Further, each conductor 195 (each strand) is located in a separate groove. As such even if the multi-filar coil of conductors 195 was considered to be a cable, it still would not be a conductor cable welded in the groove as required by the claims.

As the Westlund patent doesn't disclose a cabled conductor of the type required by the claims located in "the groove" it cannot possibly address the appropriate mechanisms for welding a multi-stranded, cabled conductor into "the groove". The Examiner expressly contends that it would be obvious to make a pre-weld diameter of the conductor to be greater than the depth of the groove. However, as noted previously, if a single strand wire conductor as illustrated in Westlund (circular cross section) were larger than the depth of the groove as illustrated [square cross section], it correspondingly would also be wider than the groove and the points of greatest resistance would create a weld pool on the surface the conductor that is outside the groove, likely causing the weld to fail. Possibly this is why in the illustrated embodiments of Westlund, the individual conductors are all shown as having diameters less than or equal to the widths and depths grooves in which they are located. If the individual strands of Westlund actually were cabled together. Westlund correspondingly would suggest that the diameter of the resultant conductor should correspondingly be less than or equal to the depth and width of any groove (singular) in which it might be welded. Therefore, to the extent Westlund has teaching relevant to the invention, it teaches the exactly the contrary. Withdrawal of the rejection is requested for this reason as well

The Examiner's opinion that "greater, equal and lesser" are all "identified alternatives" is respectfully asserted to be per-se inadequate, unless they are asserted

to be known <u>equivalent</u> alternatives. Not all known alternatives are necessarily substitutable for one another, particularly where the alternatives include exact opposites as in the present case. To take a scriptural example, "Thou shalt kill" is not a useful substitute for "Thou shalt not kill" in most situations, even though they are known alternatives to one another.

The Examiner's opinion is further asserted to be erroneous for at least the following five specific reasons:

First, "greater, lesser and equal" are seldom considered equivalents to one another. Ask any engineer, carpenter, cook or mechanic.

Second, there is no mention of where these alternatives are "identified" as being equivalent.

Third, within the teaching of Westlund, the express teaching is clear that the diameter of a conductor should be less than or equal to the depth of the recess (groove or bore) in which it is mounted.

Fourth, in the claimed context of resistance welding, these would not in fact be equivalent alternatives in the case of single strands conductors welded in to grooves the reason discussed above. If the Examiner has some reference which discloses that all three "identified alternatives" have in fact been identified as equivalents in the context of resistance welding of single stranded conductors, this reference should be cited.

Fifth, even if these three alternatives could be considered as obvious equivalent alternatives in the case of welding single stranded solid wires as disclosed in Westlund, the argument still does not address the questions associated with welding cabled stranded conductors as required by the claims. If the Examiner has some reference which discloses that all three "identified alternatives" have in fact been identified as equivalents in the context of resistance welding of cabled stranded conductors, this reference should be cited.

For at least the foregoing reasons, Applicants assert that the rejection of claims 1 - 6, 8 - 13, 25 and 29 over Westlund fails to meet the standard of common sense and should be withdrawn

In response to the above arguments, the examiner's response was as follows:

"However, the Examiner submits that the claim does not require a multi-strand cable but rather a plurality of wire strands cabled together."

It is respectfully asserted that a "plurality of wire strands cabled together" is the definition of "a multi-strand cable". Therefore, it is respectfully asserted that this statement, however it may be interpreted, does not in any way address the deficiencies in the rejection as set forth above. Rejections of this sort (single reference Section 103) must meet the standard of common sense and must be set forth with sufficient specificity to show that the standard is met. (Perfect Web Technologies, Inc. v. InfoUSA,Inc.) This statement does not meet the required standard. As the rejection apparently relies upon this statement, the rejection is respectfully asserted to be improper for this reason as well

If the Examiner is arguing that Applicant's failure to exactly quote the language of the claims in the argument somehow renders the claims unpatentable, Applicants must respectfully note that the grounds for unpatentability are set forth in Sections 102 and 103 and this isn't one of them. For the sake of completeness, however, it is respectfully noted that the above arguments are exactly the same whether the term "multi-strand cable" or "plurality of wire strands cabled together" is used to describe the conductor.

# B. Rejection Under 35 U.S.C. § 103 - Rejection over Ley (U.S. 6, 912,423) in view of Bush (U.S. 5,385,578)

Claims 1-6, 8 - 13, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ley (U.S. 6, 912,423) in view of Bush (U.S. 5,385,578). This rejection is also respectfully traversed.

In the Final Action, the Examiner does not dispute that the diameter of the conductive core of Ley is equal to the depth of the groove. The Examiner instead argues that the outer diameter of the insulation ("diameter of the filar") is still greater than the depth of the groove. This is not disputed by applicants. However, the

obviousness of adding a resistance weld to this particular disclosed connection geometry is respectfully traversed for two reasons.

First, as known to the art and as described in the present application, resistance welding is typically accomplished by placing oppositely polarized electrodes on either side of the intended weld site, each in electrical contact with only one of the two metal components to be welded, with the intended weld occurring between the electrodes. In Ley, after insertion of the insulated conductor into the groove, the surface of the "filar available opposite the intended weld site is covered with insulation, making a resistance weld impractical, or at the very least a bad idea. Yes, the insulation could theoretically be stripped off, but the expressly stated benefit of the connection as disclosed in Ley is avoiding the necessity of performing this step. Adding a process (resistance welding) to the disclosed connection geometry would thus necessitate removal the intended benefit of the connection geometry of Ley and therefore cannot be an obvious modification.

Second, the connection geometry in Ley is intended to provide an alternative to welding, and to avoid the necessity of welding altogether. As such using a resistance weld in conjunction with the connection geometry of Ley would defeat its basic purpose and cannot reasonably be argued to be an obvious modification. This is true regardless of the fact that resistance welding generally is a well known mechanism for joining two metal components and is generally referenced in Ley, Bush and many other prior art patents.

The present invention as claimed is directed to a specific improvement to a resistance welding process. The geometry of Ley is intended to provide an alternative to welding altogether. It is respectfully asserted that the Examiner's proposed addition of a resistance weld to the connection geometry of Ley is thus contrary to common sense and the rejection is thus inadequate as a matter of law.

For at least the foregoing reasons, Applicants assert that the rejection of claims 1-6, 8 - 13, and 25 based on Ley and Bush is improper and should be withdrawn.

Claim 29 was not rejected over Ley in view of Bush in the Final Office Action and so should be allowable over Ley and Bush regardless of the patentability of claims 1 – 6.8 – 13 and 25 over these same references.

Applicant respectfully asserts that the present claims are in condition for allowance. Withdrawal of the instant rejections and issuance of a Notice of Allowance is respectfully requested.

Respectfully submitted,

August 6, 2010 Date /Reed A. Duthler/ Reed A. Duthler Reg. No. 30,626 (763) 526-1564 Customer No. 27581

## VIII. Claims Appendix

The claims appealed are as follows:

A medical electrical lead, comprising:

a component including a surface and a groove formed in the surface:

a conductor, the conductor extending within the lead and including a plurality of wire strands cabled together positioned within the groove of the component; and

a resistance weld formed between the conductor and the component;

wherein the groove includes a depth and the conductor positioned within the

groove includes a pre-weld diameter, the pre-weld diameter being greater than the

depth of the groove.

2. The medical electrical lead of claim 1, wherein the surface has a curved profile.

3. The medical electrical lead of claim 2, wherein the component comprises a

substantially tubular body and wherein the surface is an inner surface of the

substantially tubular body.

4. The medical electrical lead of claim 2, wherein the surface of the component

forms an outer diameter.

5. The medical electrical lead of claim 2, wherein the surface of the component

forms an inner diameter and the component further includes an outer electrode surface.

6. The medical electrical lead of claim 5, wherein the outer electrode surface

includes a titanium nitride coating.

(Cancelled)

8. The medical electrical lead of claim 1, wherein the conductor is a coil.

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The medical electrical lead of claim 1, wherein the groove extends approximately aligned with a longitudinal axis of the component.

10. The medical electrical lead of claim 1, wherein the groove extends approximately transverse to a longitudinal axis of the component.

11. The medical electrical lead of claim 2, wherein the groove spiraling about a portion of a circumference of the surface.

12. The medical electrical lead of claim 1, wherein the groove includes an approximately semi-circular cross-section.

13. The medical electrical lead of claim 1, wherein the groove includes an approximately v-shaped cross-section.

14 - 24 (Cancelled)

25. The medical electrical lead of claim 1, wherein the component comprises an elongated body, and wherein the groove comprises a longitudinal slot substantially parallel with the longitudinal axis of the elongated body.

26 - 28. (Cancelled)

# 29. A medical electrical lead, comprising:

a component comprising a substantially tubular body having an inner surface and a groove formed in the inner surface;

a conductor comprising a plurality of wire strands cabled together, the conductor extending within the lead and positioned within the groove of the component; and

a resistance weld formed between the conductor and the component:

wherein the groove includes a depth and the conductor positioned within the groove includes a pre-weld diameter, the pre-weld diameter being greater than the depth of the groove.

### IX. Evidence Appendix

The following patents from Medtronic's competitors are just a few of the available examples which illustrate that their usage of the term "cable" to describe a conductor is the same as Medtronic's and does not apply to a multi-filar coil of solid wires as in Westlund. Numerous Medtronic patents also employ this nomenclature, but it believed that these would be cumulative to the present application, which discloses Medtronic's usage of the terms. These terms are also used in the technical manuals describing the products to the physicians that purchase them, so the terms are correspondingly also understood by the medical community. If there is any disagreement by the Examiner that these are in fact the common usages usages of these terms in the relevant art of medical leads, additional exhibits can and will be provided. The terms cable, cable conductor and cabled conductor are all well understood by those of skill in this art area to be distinct from coiled solid conductors as disclosed in Westlund.

As the Patent Office has copies of these references, it is understood that complete copies need not be submitted.

# United States Patent [19] Bartig et al.

1541	MONORAIL LEFT VENTRICULAR ACCESS
	TEAD

- [25] Inventors. Jeffrey T. Bartig, Moplewood: Randy Peterfess, St. Psul, both of Minn.
- [73] Assignor Cardine Paremokers, Inc., St. Paul, Minn
- [21] Appl. No.: 89/139,454
- [22] Filed. Aug. 25, 1998
- [51] Int. Cl. A61B 56H2 [52] U.S. Cl. 607/122, e07/125, GR6393 [58] Field of Search 607/122, 125.
- [56] References Cited

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145]	Date of Patent:	Oct. 10, 2000

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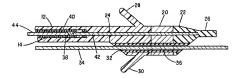
Primary Examiner -- Carl H Layare

Attorney, Agent, or Firm—Nikolas, Mersettan & Dietz, P.A.

1873 ABSTRACT

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6 Claims, 2 Drawing Sheets





# an United States Patent Chastain et al. (34) COMPOSITE WIRE FOR IMPLANTABLE

(10) Patent No.: (45) Date of Patent:

US 7,612,291 B2 Nov. 3, 2009

		COILS	: LEAD CONDUCTOR CABLE AND	
1	75)	luveutors	Stuart B. Chastain, Shoreview, MN (US), Russell L. Hucker, Maple Gurve, MN (US)	
ŧ	73)	Assigney.	Cardiac Pacemokers, Inc., St. Prol. MN (US)	
(	*3	Notice:	Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.	
ŧ	21)	Appl No.:	11/558,147	
0	22)	Piled:	New, 9, 2006	

Prior Publication Data

US 2007/6154729.A1 Jul. 5, 2007 Related U.S. Application Data

(60) Provisional application No. 60/735,296, filed on Nov. 10, 2005.

(51) Bat. Cl. 1101B 5/19 (2006.01) (52) U.S. Cl. .... ..... 174/126.1 See application life for complete search history.

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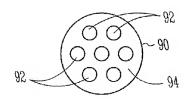
05-126321 \* 5 1993 o cited by examiner

Primary Examiner -- Chan N Nguyen (74) Autorney, Agent, or Firm Schnegman, Lunchen, & Woossaer, P.A.

ABSTRACT

A composite ware can include a core including a material chosen from the group consisting of Ag and ir and combina-tions thereof. a shell around the core including a material classes from the group consisting of Ta, MF35N, and Nb and combinations thereof, and as outer layer over the shell including a material chosen from the group consisting of PI and Pt.-. is and combinations thereof.

22 Claims, 3 Drawing Shorts



# USANG SPECIES

# United States Patent

DIAMETER OF SLEEVE

(10) Patent No.: US 6,650,921 B2 (45) Date of Patent: Nov. 18, 2003

# (54) CARDIAC LEAD WITH MINIMEZED INSIDE

(75)	laveasors	Paul R. Spehr, Lake Inckson, TX (US), Elmar R. Fischer, Sr., Lake Inckson, TX (US), James E. Machek,
		Loke Bickson, TX (US)

- (73) Assignce: Intermedics Inc., Angleton, TX (US)
- (\*) Notice. Subject to any disclaimer, the term of this patern is extended or adjusted under 35 U.S.C. 154(N) by 0 days.
- (21) Appl. No.: 89/994,389
- (22) Filiad: Nov. 26, 2001
- (id) Prior Publication Date

US 2/802/03/82/312 AT May, 21, 2002

### Related U.S. Application Data

(0.)	1997, per Pai. No. 6,334,415.
(51)	Int. CL1
(52)	U.S. Cl 600/374, 600/375; 607/110,
	687/122; 607/126
(58)	Field of Search 607/101-102.
	607, 122, 126, 127, 129, 119, 116, 128;

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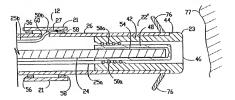
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Primary Examiner—Linds C. M. Dvorsk Assistant Examiner—Uxed M Roddy (74) Anterior Agent or Prim—Schwegman, Lundbarg, Westster & Klath, P.A.

### (57) ABSTRACT

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# 19 Claims, 7 Brawing Sheets



600/372-377

# **United States Patent**

US 6,181,971 B1 (10) Patent No.:

(54)	JOINING CONDECTOR CABLES AND
	ELECTROBES ON A MEETI LUMEN LEAD
	Respec

(75) Inventor. Phong D. Dann, Stevenson Ranch, CA 8:51

patent shall be extended for O days.

- (73) Assignor: Pacesetter, Inc., Sylvar, CA (US) (\*) Notice. Under 35 U.S.C. (54(6), the term of this
- (21) Appl. No.: 09/268,234
- (22) Liled Dec. 9, 1998 .. ANIN 1895 (58) Field of Search

# ech 607/116, 117. 607/116, 119, 122, 600/372, 373, 374, 375, 377 (56) References Cited

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(48) Date of Patent: Jan. 30, 2001

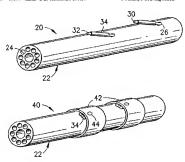
5,409,081 \$35% Kords . U1997 Von Esp \$1997 Quadras et al. . 5,548,142 5.678,094 its/1977 Boser of all

" cited by examiner

Primary Examiner-George R. Evanisko ABSTRACT

An empiantable medical electrical lead is made by forming a generally radially dimeted have extending between each a generally remaily intracted tout resembling between rank-limen of an elongated lead touty having a plurality of internal forgitudinally extending, circumsterentially spaced luming, the hores being located at kengitadmally and circenturentially spaced locations, then drawing an elongated conductor cable into and through each hunce of the lead body such that a terminal end through projects through and beyond an associated one of the bores. A metallic take is slidably attached outs each enoductor cable adjacent the cable's terminal and, then is limity joined to its associated conductor cable. Thereupon, each metallic time is affixed, as by welding, preferably, by laser welding, to in associated use of a plorality of tubular electrodes couxiel with, and overlying, the lead tody at longitudically spaced locations In our instance, the tabular electrode sucy by a ring electrode with the lead body connected to a pacentaker in another instance, the tobular electrode may be a shock god electrode with the lead body connected to a defibrillator.

6 Chinns, 3 Drawing Sheets



# ittl Patent Number:

United States Patent 1001 5.851,227 Spehr [45] Date of Patent: Dec. 22, 1998

# [54] CARDIAC PACEMAKER CABLE LEAD

1751 Inventor Paul R. Spehr, Lake Jackson, Tex.

[73] Assignce: Suizer Intermedies Inc., Angleton, Tex.

1211 Appl. No.: 903,363

122) Filed: Jul. 30, 1997

. A61N 1/95 [52] U.S. CL. 607/126: 607/122; 607/116 

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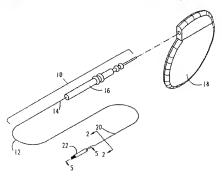
Prenary Emonitor William E. Kenner Assessmer Examiner-Carl H. Layno

Anorsey, Agent, or Firm-Acan R. Merkling; Timothy M. Honoroutt

### ABSTRACT

A lead assembly adapted for endocardial fizzation to a turnon heart is necouled. The least assembly includes a least body that has a possional and provided with a connector for electrical connection to a cardina stimulator. The eartise stimulator may be a pacemoker, a cardiovertexylefitailiann, or a sensong instrument. The districted of the lead body is connected to a tubular electrode bousing. The lead body consists of a generalised conductor cable surrounded by a eneweasive insulating sleeve. In contrast to conventional leads, the lead body of the present love stion does not require chiled conductor wires or an internal tumes. Manipulation of the lead body is via an emental guide tube. Lead body diameters of 0.25 mm or smaller are possible.

#### 19 Claims, 6 Drawing Sheets



# X. Related Proceedings Appendix

None.